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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/983,474	06/30/1998	DAVID KLATZMANN	31649-134353	1470

7590

07/16/2002

VENABLE  
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WASHINGTON, DC 20005-3917

EXAMINER
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BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/16/2002

*L2*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**08/983,474**

Applicant(s)  
**KLATZMAN et al**

Examiner  
**Nirmal S. Basi**

Art Unit  
**1646**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 26, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17, 20, and 22-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-12, 17, 20, 23, and 26 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 13-16, 22, 24, and 25 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20 6) ☐ Other:

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**DETAILED ACTION**

1. Amendment filed 4/26/021 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (3/21/00, paper number 13).

5                                   **Claim Rejection, 35 U.S.C. 112, second paragraph,**

3. Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10                   Claims 4 remains indefinite as it is not clear what are proteins of the “CD type” so as to allow the metes and bounds of the claim to be determined. Applicant states the term “CD type” means the family of Cluster differentiation antigens and provides chapter 61 from the reference book edited by Herzenberg. Applicants arguments have been fully considered but not found persuasive. The term “CD type” carries no weight in terms of structure and function and reads on unrelated proteins, the metes and bounds of which can not be determined based on prior art and the specification. It is  
15                   not clear when a protein is of “CD type” as compared to when it is not of the “CD type. Specifically what structure identifies the polypeptide to be a “CD type” as compared to it not being the CD type. Applicant is requested to specifically disclose where in the Herzenberg reference the meaning of “CD type” is disclosed and it is an art accepted term so as to allow the metes and bounds of the claim to be determined.

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Claims 5 and 6 are rejected for depending on an indefinite base claim and fail to resolve the issues raised above.

5. **Claim Rejections, 35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1, 4-11, 17, 20, 23 and 26 is maintained under 35 U.S.C. 102(b).

Applicant argues Biogen publication does not disclose a recombinant multimeric protein comprising the alpha chain of C4BP and the beta chain of C4BP, the structure of the beta chain were unknown at the time the Biogen publication was filed. Applicants arguments have been fully considered but not found persuasive. Biogen discloses, "In addition to seven C4bp monomers, human C4bp contains another subunit, a 45 kD polypeptide which is linked by disulfide bonds to the C4bp heptamer core", page 4, lines 12-17. The 45 polypeptide of Biogen is presumed to be the beta chain, absent evidence to the contrary.

Claims 1, 4-11, 17, 20, 23 and 26 remain rejected, and claim 12 is newly rejected under 35 U.S.C. 102(b) as being anticipated by Biogen Inc (IDS Ref AH, see previous Office action). Biogen Inc. disclose a recombinant multimeric protein comprising the alpha chain of C4BP and the beta chain of C4BP wherein monomer are linked by disulfide bonds (pages 5-7, for example). Further disclosed are that the multimeric fusion polypeptide can conation fusions comprising

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immunoglobulins, antigens , CD4 type proteins and therapeutic enzymes (pages 9-31) , absent evident to the contrary. Also disclosed are host cells containing the recombinant polypeptide and methods of producing recombinant polypeptide.

5            Claims 2-3, 13-16, 22, 24-25 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Advisory Information

10            Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

15            If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

20            Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
25    July 15, 2002

*Michael D. Pak*  
MICHAEL PAK  
PRIMARY EXAMINER